

## REMARKS

### Allowed/Allowable Claims

Claim 62 has been indicated to be allowable if rewritten in independent form to include the subject matter of independent claim 1 from which it depends. To that end, the Applicant has rewritten claim 62 in independent form, and allowance of the same is respectfully requested.

### Claim Rejections – 35 U.S.C. § 103

Claims 1-7, 10-11, 16-23, 29-31, 33, 34, 43, 53, 58-61 and 63-64 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,217,578 to Crozet et al. in view of U.S. Patent No. 5,545,167 to Lin and in further view of U.S. Patent No. 6,267,543 to David et al., claims 8, 9, 12 and 60 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin in further view of David and in still further view of U.S. Patent Publication No. 2003/0114853 to Burgess et al., claims 13-15, 24-28, 37 and 38 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin in further view of David and in still further view of U.S. Patent No. 5,976,135 to Sherman et al., and claims 35, 36, 54, 55 and 57 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin in further view of David and in still further view of U.S. Patent No. 6,554,832 to Shluzas. Additionally, claims 39-42 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin in further via of David and in still further view of U.S. Patent No. 5,501,684 to Schlapfer et al., and claims 44-46, 49, 51, 52 and 65 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Schlapfer and in further view of U.S. Patent No. Re39,035 to Finn et al.

### Claim Amendments

Independent claims 1, 44 and 53 have been amended to recite further features associated with the claimed invention. Additionally, as indicated above, claim 62 has been rewritten in independent form.

### Arguments in Support of Patentability

The seminal case directed to application of 35 U.S.C. §103 is *Graham v. John Deere*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). From this case, four familiar factual inquiries have resulted.

The first three, determining the scope and content of the prior art, ascertaining differences between the prior art and the claims at issue and resolving the level of ordinary skill in the pertinent art, are directed to the evaluation of prior art relative to the claims of the pending application. The fourth factual inquiry is directed to evaluating evidence of secondary considerations. See Manual of Patent Examining Procedure (MPEP) §2141. While performing this analysis, the cited references must be considered in their entirety, i.e., as a whole, including portions that would lead away from the claimed invention. See, MPEP §2141.02 (citing W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)). From these inquiries, the initial burden is on the Examiner to establish a *prima facie* case of obviousness.

Additionally, the Supreme Court in the recent decision of KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385, 127 S.Ct. 1727, 167 L.Ed.2d 705 (U.S. 2007), citing In Re Kahn, 441 F.3d 977, 988 (CA Fed. 2006), stated:

[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

KSR, 82 USPQ2d at 1396. For at least the following reasons, it is respectfully submitted that a *prima facie* case of obviousness has not been established in this case.

#### Independent Claim 1 and Dependent Claims 2-31, 34-43, 59-61 and 63

As indicated above, independent claim 1 stands rejected as being unpatentable over Crozet in view of Lin and in further view of David.

As an initial matter, the Applicant respectfully traverses the use of David in support of the obviousness rejection of independent claim 1. Pursuant to the obligation to determine the appropriate scope of prior art in accordance with Graham, the MPEP indicates that to rely on a reference under 35 U.S.C. §103, it must be analogous prior art. (See MPEP §2141.01(a)). More particularly, “[i]n order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.” (See MPEP

§2141.01(a) citing In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992)). The Applicant respectfully submits that David is not analogous art.

Independent claim 1 is directed to a cross-connector assembly for interconnecting a pair of orthopedic rods. As might be expected, the first two references (Crozet and Lin) cited in the Office Action against independent claim 1 are entitled “Spinal Cross Connector” and “Retaining Mechanism of Vertebral Fixation Rod.” In contrast, David has nothing to do with an intervertebral connector. Instead, David discloses at column 1, lines 8-9 that “[t]he present invention relates to fasteners for removably securing together two panels or other objects”, while the Abstract indicates that the disclosed system can be used in network interface devices and plastic enclosures. Moreover, a further review of David clearly establishes that it is directed to providing alternative fasteners to the computer industry, “where it is desired to attach various loose-fitting components and covers in a positive secure fashion”. (See, column 1, lines 20-25).

As expected, the Applicant has found no mention in David of any system, apparatus or device for interconnecting a pair of orthopedic rods. Consequently, David is clearly not in the same field of endeavor as the subject application, nor has the Office Action provided any reasonable indication or suggestion of the same.

It must also be considered whether David is reasonably pertinent to the particular problem of the subject application. The standard for making this determination is:

A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem. Thus, the purpose of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve. If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it.

In re Clay, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992).

The Applicant notes that David does not deal with any problem having a logical connection to the present invention. Instead, David addresses problems associated with the

connection of loose fitting components in light industrial applications such as the computer industry. (See column 1, lines 20-25). Moreover, David discloses no purpose that reasonably relates its fasteners for use in solving the problem addressed by the present invention. The present invention provides apparatuses, systems and devices for interconnection of orthopedic rods that, in one form, allow an interconnection device to be provided as a completely assembled unit that does not inadvertently become dissembled prior to or during implantation, while also allowing the members of the interconnection device to be moved relative to one another to a desired orientation. (See e.g., Abstract and paragraph [0009]). The purpose of David is to provide alternative fasteners for industrial applications such as the computer industry “where it is desired to attach various loose-fitting components and covers in a positive secure fashion”. (See column 1, lines 20-25). Since the purpose of the arrangement in David addresses problems which are so unrelated to the problem addressed by the present invention, one of ordinary skill in the art would have no motivation to consider it. Thus, David is clearly non-analogous art that cannot be fairly/reasonably used in support of the obviousness rejection of independent claim 1.

Additionally, it is respectfully submitted that the rationale necessary to support further modification of the Crozet/Lin combination as required by KSR has not been set forth in the Office Action. The Office Action asserts that it would have been obvious to substitute the double lobe design of the Crozet/Lin combination with the single lobe design of David “in order to achieve the predictable result of allow [sic] the lobe to pass through the aperture”. During prosecution of the subject application, the Patent Office has taken the position that Lin “teaches a lobe that must be rotated to fit and lock the end of a shaft through an aperture”, and that the modification to Crozet “is being made to the aperture and the end of the shaft”. (See pages 14-15 of the May 10, 2010 Office Action). In view of this position, it appears the suggested modification of Crozet would include replacing the flange 62 on the arm 28 with the rectangular head 220 of Lin, and providing the bore 58 through the pivot element 44 with a rectangular configuration that corresponds to the rectangular configuration disclosed in Lin for the holes 430, 530, 630 and 730 through components 400, 500, 600 and 700, respectively. In this arrangement, the rectangular head 220 would already be allowed to pass through the bore 58. As a corollary, since the Crozet/Lin combination already allows a lobe to pass through an aperture, those skilled in the art would have no reason to, and consequently would not, further modify the Crozet/Lin

for the reason provided by the Office Action. Accordingly, the rationale required by KSR has not been provided, nor has a *prima facie* case of obviousness been established.

Notwithstanding the foregoing, and without acquiescing in the current rejection, independent claim 1 has been amended in order to advance prosecution of the subject application toward allowance. Independent claim 1 now recites, in combination with other elements and features:

a first rod connector including a first shaft terminating in a first rod engaging portion and a lobe extending laterally from an end of said first shaft and displaced axially along said first shaft from the first rod engaging portion, wherein in a first orientation between said first rod connector and said interconnection element a portion of said first shaft and said lobe are slideably positionable within the first aperture such that said lobe passes through said first aperture and upon rotation of said first rod connector relative to said interconnection element from said first orientation to any other orientation said lobe prevents said first rod connector from being removed from said first aperture;

a second rod connector including a second shaft having a second body carried thereon, said second body having a second aperture formed therein, said second aperture having the stud received therein; and

a fastener configured to engage with the stud; and

wherein upon rotation of said first rod connector relative to said interconnection element from said first orientation to said other orientations said first rod connector remains axially slid able relative to said interconnection element until said assembly is secured with said fastener.

Support for the amendment to independent claim 1 is found, for example, in Figures 1 and 2 and paragraph [0057] of the published version of the subject application (i.e., U.S. Patent Application Publication No. 2004/0133203).

In contrast to the arrangement now recited in independent claim 1, David teaches that axial sliding of the bolt 102 relative to the panels 104, 106 is prevented once it is rotated away from the rectangular slots 128, 136. (See Figure 3 and column 4, lines 53-60). Thus, even assuming arguendo that the double lobe design of the Crozet/Lin combination is replaced by the single lobe design of David (as suggested by the Office Action), the resulting arrangement would still not satisfy independent claim 1. Accordingly, independent claim 1 is patentable for this additional reason.

For at least the reasons set forth above, the Applicant submits that independent claim 1 is patentable over the cited references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 1 and allowance of the same.

Claims 2-31, 34-43, 59-61 and 63 depend either directly or indirectly from independent claim 1 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 1, although further reasons support the patentability of these claims, including many of those submitted by the Applicant in the previous response.

**Independent Claim 44 and Dependent Claims 45, 46, 49, 51, 52 and 64**

As indicated above, independent claim 44 stands rejected as being unpatentable over Crozet in view of Schlapfer and in further view of Finn. Without acquiescing in this rejection and in order to advance prosecution of the subject application toward allowance, independent claim 44 has been amended and now recites, in combination with other elements and features:

an insert positioned over said stud having a lower surface with a concave portion configured to engage the first shaft of the first rod connecting member on opposite sides of said stud and an upper portion positioned in said first aperture of said second body.

Support for the amendment of independent claim 44 is found, for example, in paragraph [0075] and in Figures 13, 14a and 14b of the published version of the subject application. For at least the reasons that follow, it is respectfully submitted that independent claim 44 is patentable over the cited references.

The Office Action asserts that the Crozet/Schlapfer combination discloses all of the features of independent claim 44 “except for the insert having a lower surface having a concave portion”. (See page 16). However, the Office Action suggests modifying the insert of Schlapfer in view of Finn to include a concave bottom surface. Even assuming arguendo that the Crozet/Schlapfer combination were modified in this manner, the Applicant notes that the arrangement recited in independent claim 44 regarding “an insert positioned over said stud having a lower surface with a concave portion configured to engage the first shaft of the first rod connecting member on opposite sides of said stud” would still not be satisfied. Notably, as illustrated in Figure 3 of Crozet, the shaft 28 only extends through the surface 46 on one side of the threaded portion 50, and would only be engaged by an insert on one side of the threaded

portion 50. Accordingly, the Crozet/Schlapfer/Finn combination fails to account for the subject matter of independent claim 44 as a whole.

For at least the reasons set forth above, the Applicant submits that independent claim 44 is patentable over the cited references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 44 and allowance of the same.

Claims 45, 46, 49, 51, 52 and 65 depend either directly or indirectly from independent claim 44 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 44, although further reasons support the patentability of these claims, including many of those submitted by the Applicant in the previous response.

**Independent Claim 53 and Dependent Claims 54, 55, 57, 58 and 64**

As indicated above, independent claim 53 stands rejected as being unpatentable over Crozet in view of Lin and in further view of David. For the reasons set forth above with respect to independent claim 1, David is non-analogous art that cannot be fairly used in support of an obviousness rejection of independent claim 53. Moreover, the rationale required by KSR is also missing, as also discussed above in connection with independent claim 1.

Notwithstanding the foregoing, and without acquiescing in the current rejection, independent claim 53 has been amended in order to advance prosecution of the subject application toward allowance. Independent claim 53 now recites, in combination with other features and elements:

wherein said first spinal rod connector is axially slid able relative to said interconnection device when said first shaft is in said other orientations until said assembly is secured with said fastener.

Support for the amendment to independent claim 53 is found, for example, in Figures 1 and 2 and paragraph [0057] of the published version of the subject application.

For reasons similar to those set forth above in connection with independent claim 1, the Crozet/Lin/David combination fails to account for an arrangement “wherein said first spinal rod connector is axially slid able relative to said interconnection device when said first shaft is in said other orientations until said assembly is secured with said fastener”. Accordingly, independent claim 53 is patentable for this additional reason as well.

For at least the reasons set forth above, the Applicant submits that independent claim 53 is patentable over the cited references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 53 and allowance of the same. Claims 54, 55, 57, 58 and 64 depend either directly or indirectly from independent claim 53 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 53.

## CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the subject application is now in condition for allowance with pending claims 1-31, 34-46, 49, 51-55 and 57-65.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,



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